REMARKS

This paper is responsive to the Office Action dated August 11, 2004, which is the second action on the merits of the application. The Action has been made final.

Claims 23-47 are pending in this application, with claims 34-46 under examination. By way of this Response, independent claims 34 and 35 have been amended.

Applicant gratefully acknowledges withdrawal of the objection to the specification, and the rejection of the claims previously made under 35 USC § 112 ¶ 2. The claims remain rejected under the description and enablement requirements of § 112 ¶ 1.

Accompanying this response is a Notice of Appeal, which effectively extends the pendency of this application.

Reconsideration and allowance of the application is respectfully requested.

Summary of Interviews

The undersigned gratefully acknowledges the courtesy of Examiner Anne-Marie Falk and Examiner Deborah Reynolds for the courtesy of an interview at the Patent Office on September 1, 2004. Possible approaches to product claims for pPS derived neural cells for overcoming the issues of record were discussed.

Entry of this Response under 37 CFR § 1.116

Applicant believes that the amendments to the claims will place all or at least some of the claims into condition for allowance. In any event, applicant requests that this paper be entered into the file, since the amendments to the claims and the remarks that follow facilitate consideration of the outstanding issues.

Claim amendments:

Entry of the claim amendments does not introduce new matter into the disclosure. Support for the new wording may be found at various places in the specification; *inter alia* page 17, lines 25-34; and Example 5 (pp. 33-35). Coverage is maintained for all equivalents of the claimed subject matter for which applicant was previously entitled.

Rejections under 35 USC § 112 ¶ 1:

Claims 34-46 stand rejected under § 112 ¶ 1 as not being described in the specification so as to convey to the skilled reader that the inventor had possession of the claimed subject matter.

The Office Action argues that a *system* for producing neural cells, comprising both the pPS cell population and the neural cell population, does not meet the written description requirement because: 1) The *system* can also include Geron Corporation; and 2) It is uncertain as to when each of the two cell populations are in possession of the user.

Applicant respectfully submits that the first point does not raise a patentability issue under § 112 ¶ 1, because the practice of any invention (claimed as a product or as a method) will necessarily entail a place of manufacture. Since the actual place of manufacture chosen by the user is not critical to the practice of the invention, provided it otherwise meets the requirements of the manufacturing method. It is therefore not necessary to state the place of manufacture in the claim. Thus, the question of patenting legal entities such as Geron Corporation does not arise.

With respect to the second point, applicant respectfully submits that the time of possession of each cell population also does not raise a patentability issue under § 112 ¶ 1. As indicated in the previously submitted 35 USC § 1.132 Declaration by Dr. Thies, the skilled reader will know the inventor had possession of the two cell populations from the disclosure as filed. The skilled reader will also know that they are practicing the invention defined in the claims when they possess the two cell populations either at the same time or sequentially. Determination that a user is infringing the claims under 35 USC § 271 is a matter for the courts to decide, and is outside the jurisdiction of the U.S. Patent & Trademark Office.

Claims 34-46 also stand rejected under § 112 ¶ 1 as not enabling the skilled reader to make or use the invention.

The pending Office Action does not challenge enablement of the making of the invention — which is appropriate, because the specification clearly explains and illustrates how the skilled reader can make the two cell populations recited in the claims. However, the Office Action indicates that the specification does not specifically disclose *how to use* these two cell populations *together*.

Applicant respectfully disagrees. The enablement requirements of § 112 ¶ 1 are satisfied for a *product* claim when the specification enables at least one way of making the product, and at least one way of using the product. Where the product has multiple components, it is not necessary for the components to be used together.

By way of illustration, consider claim 22 of recently issued U.S. Patent No. 6,740,649:

> 22. An article of manufacture, comprising:
>
> (a) a first container;
>
> (b) a pharmaceutical composition located within the first container, wherein the composition, comprises: a first therapeutic agent, comprising: a compound according to claim 1 [a hydroxamic acid] or a pharmaceutically acceptable salt form thereof; and,
>
> (c) a package insert stating that the pharmaceutical composition can be used for the treatment of a thromboembolic disorder.

The components of this type of pharmaceutical claim are not used at the same time. The specification of the '649 patent presumably is enabling for the use of pharmaceutical composition in clinical therapy. However, until it is administered to the patient, the composition is *not being used for anything*. The container, on the other hand, is used for safely protecting and transporting the composition, *but is not administered to the patient.* The package insert will typically be discarded, but it may occasionally be read by the patient or the health care provider: as a separate activity from either the transporting of the composition, or the administration of the composition. Thus, each of the three components of the claimed composition has utilities at a different time for a different purpose — but all aimed to provide therapeutic benefit for the patient.

The specification of the present application discloses and enables a number of uses for the two components of the claim:

1. Production of neuronal cells from hES cells for any purpose, including but not limited to use in clinical therapy. First, the hES cells can be bulked up in culture in undifferentiated form (illustrated in Example 1, p. 25 ff.). The hES cell culture is then differentiated into neural cells according to the methods described (illustrated in Example 5, p. 33 ff.), optionally keeping a portion of the hES cell population in an undifferentiated form as a reserve for further manufacturing. The neural cells in turn are used for compounding in a pharmaceutical composition (page 25, lines 5-11), or any other worthwhile purpose. Thus, in one embodiment, the hES cell population and the neuronal cell population are used simultaneously or sequentially for the manufacturing of pharmaceuticals.

2. Preparation of antibody specific for undifferentiated hES cells. Page 21, lines 16-20 teaches that specific antibody can be obtained by positively selecting using [undifferentiated] pPS cells, and negatively selecting using differentiated embryonic cells.

3. Generation of subtraction libraries. Page 21, lines 21-25 teaches that mRNA extracted from both differentiated and undifferentiated cells can be used to produce cDNA subtraction libraries enriched for transcripts that are up- or down-regulated during differentiation. Page 23, lines 14-20 explains the use of undifferentiated and differentiated cells together to identify expression products to characterize and control the differentiation process.

Thus, the specification enables not just one, but a number of ways in which the multiple components of the claimed product can be used for a beneficial and united purpose.

For the reasons stated, applicant respectfully submits that the claims as previously presented more than adequately comply with the description and enablement requirements of § 112 ¶ 1. Nevertheless, so as to help resolve these issues, independent claims 34 and 35 have now been reworded.

Base claim 34 has been amended to refer to the product in the preamble as *a plurality of cell cultures used during production of neuronal cells from hES cells*. Base claim 35 has been amended to refer to the product in the preamble as a *plurality of cell populations generated during production of tyrosine hydroxylase positive neuronal cells from a line of hES cells*. As explained in Dr. Thies's Declaration, these encompass a central use of the claimed product, as would be apparent to the skilled reader from the specification as filed.

Applicant submits that the amended claims meet all the patentability requirements of 35 USC §§ 101, 102, 103, and 112, and are in condition for allowance.

Withdrawal of the rejections under § 112 ¶ 1 is respectfully requested.

Option of switching claim groups

MPEP § 819.01 gives the Examiner discretion to allow applicant to switch from the group under examination to a non-elected claim group where it advances prosecution of the application.

In the event the Examiner determines that the amendments and remarks presented above are insufficient to place the application in condition for allowance, a shift of the focus of examination to withdrawn claims 23-33 may help advance prosecution. Specifically, claims 23-33 cover a *method* for making neuronal cells from hES cells using TGF -β Superfamily Antagonists. The issues raised under § 112 ¶ 1 regarding cell combinations would not apply.

Under such circumstances, applicant offers to file a Request for Continued Examination, canceling claims 34-46, thereby giving the Examiner additional resources for searching and examining method claims 23-33.

Request for Further Interview

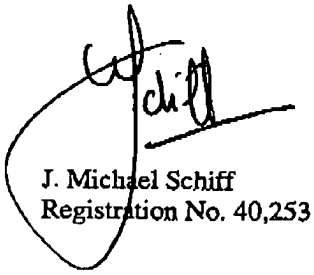
Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed with respect to the wording of the claims, or that prosecution would be further advanced by switching claim groups, applicant hereby requests a further interview by telephone.

Fees Due

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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